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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/727,534

12/05/2003

Eric P. Berg

P686 CON2

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04/02/2008

EXAMINER

GANESAN, SUBA

ART UNIT

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3774

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/727,534	Applicant(s) BERG ET AL.
	Examiner SUBA GANESAN	Art Unit 3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 3,6-8,11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2,4-5,9-10,13-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 12/28/2007 have been fully considered but they are not persuasive. Applicant argues that it would be undesirable to wash a drug eluting stent in water before use, since drug eluting stents are packaged to be sterile. This is not persuasive because it is desirable to wash a stent during manufacture and before sterilization (for example to removed unreacted substances, as suggested by Miller).
2. In response to Applicant's arguments that combination of Sahatjian with Miller et al teaching would change the principle operation of Sahatjian, attorney arguments cannot take the place of evidence. The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. (See MPEP 716.01).
3. In response to applicant's arguments that Sahatjian teaches against using a water-insoluble salt, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some

other product for the same use.” *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) Furthermore, “[t]he prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed....” *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004) (See MPEP 2123).

4. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-2, 4-5, 9-10, 13, 15-16, 18-20, 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahatjian (U.S. Pat. No. 5304121) in view of Miller et al. (U.S. Pat. No. 5,760,200).

1. Sahatjian discloses a delivery catheter, a stent framework and a porous material with a salt of a therapeutic material (see figs. 4-6 and col. 9 lines 21-34). The stent framework is made of a metal (nitinol) and can be self expanding (col. 10 lines 7-10).

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The stent framework is a combination of metallic and polymeric elements; note that examiner is considering a polymeric (hydrogel) coating on a metallic stent to be a framework comprising metallic and polymeric elements. The stent can further comprise a bioadsorbable coating (col. 9 lines 15-20). With respect to claims 13 and 15, note that examiner is further considering a coating to be a film. Sahatjian further discloses the use of heparin salt as a therapeutic salt (col. 8 lines 17-30 and col. 10 lines 1-6). However, Sahatjian does not *specifically* disclose the heparin salt being water-insoluble. Miller teaches the use of a water insoluble polyanionic polysaccharide (see abstract), which includes heparin (col. 3 lines 9-16) as a water insoluble composition in the form of a gel or film (col. 3 line 17-col. 4 line 4). Therefore it would have been obvious to one of ordinary skill in the art to modify heparin salt of Sahatjian with a water insoluble heparin composition as taught by Miller for the purpose of providing a substrate that is washable in water before use (col. 4 lines 36-38).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 14, 17, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahatjian (U.S. Pat. No. 5304121) in view of Miller et al. (U.S. Pat. No. 5,760,200), further in view of Hunter (U.S. Pat. No. 5716981).

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4. Sahatjian in view of Miller is explained supra. However, the combination does not disclose a coating of silicone or a radioactive salt. Hunter teaches the coating of stents (col. 1 lines 13-18) with radioactive materials (col. 15 lines 19-30). The stent material can be silicone (col. 16 lines 31-55). Therefore it would have been obvious to one of ordinary skill in the art to modify the stent of Sahatjian to include silicone for the purpose of creating a less rigid stent to minimize local tissue trauma and facilitate insertion within the body. It would have further been obvious to one of ordinary skill in the art at the time of the invention to modify the therapeutic salt of Sahatjian to include a radioactive material as taught by Hunter for the purpose of providing anti-angiogenic therapy at a specific location.

5. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sahatjian (U.S. Pat. No. 5304121) in view of Miller et al. (U.S. Pat. No. 5,760,200), further in view of Tang et al. (U.S. Pat. No. 4920203).

6. Sahatjian in view of Miller is explained supra. However the combination does not disclose the therapeutic salt being a barium salt. Tang teaches the use of Barium salts for a therapeutic coating on stents (col. 20 lines 41-62). Therefore it would have been obvious to one of ordinary skill in the art to modify the therapeutic salt of Sahatjian to be Barium as taught by Tang for the purpose of creating a radiopaque stent.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Suba Ganesan/
Examiner, Art Unit 3774

/William H. Matthews/
Primary Examiner AU 3774